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Dr. Wendy Baldwin Oral History 2002

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Wendy Baldwin, Ph.D.

Oral History Transcript

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Interview with Wendy Baldwin, Ph.D., Deputy Director for Extramural Research at the National Institutes of Health. Interviewer is Dr. Victoria Harden, the NIH historian. The subject of the interview is Dr. Baldwin's career at the National Institutes of Health.

Please note: this is a raw transcript—please direct any questions to the Office of History

Harden: Dr. Baldwin, let's begin with your growing up. Would you tell me about where you grew up, what your early life and education were like, and how you chose to attend Stetson University?

Baldwin: I grew up outside of Philadelphia. I was always a good student. I always assumed I would go to college. I was the first in my family to go to college. I chose Stetson because it was a strong liberal arts school. We were living in Florida then, and it was nearby. When you're the first in your family to do something, you don't necessarily know a whole lot about how you would do that. It turned out to be an excellent choice. It was a small school. I was in an honors program that was stimulating and a tremendous growth experience.

I took a course in the social sciences, understanding how societies function and what drives group behavior and what influences group differences in a society, and it was like a revelation: "Oh, that's what I want to understand!" The next semester, I took a course in population, and I immediately felt: "Well, that's it. That's what I have to do." I was in my first semester in my sophomore year, and I knew what I wanted to do. Before that, I don't think I could have told you that there were demographers, much less what they did. It was riveting.

I structured all my undergraduate years around understanding demography, fertility, reproductive behavior. We had a little "minimester" that I spent in a clinic looking at family planning programs, what actually happens when women encounter these clinics and so on, and at prenatal care and reproductive health. I was absolutely clear in my vision that these were the issues that galvanized me.

I got married while I was a student, moved to New York, and discovered that there was absolutely, positively nothing in my field you could do with a B.A. It didn't matter that it was *magna cum laude.* There was nothing you could do. It didn't matter that I was a woman or where I was from. There was no job available.

So I became a social worker, and that was really fun. I liked the human-interaction part of that. I didn't like the bureaucracy part of that. I find it ironic since I ended up a bureaucrat, but . . . I did that for a while.

Harden: Let me just back up for a follow-up question. You said you were in Florida before you started college. Was your family moving around?

Baldwin: My family moved to Florida my last year of high school, which was a terrible thing to do to a child, and so, since I was in Florida, then I had to go to a Florida school.

Harden: What population did you work with as a social worker during that year you were a social worker?

Baldwin: I was a social worker on Long Island, and I had the Lake Ronkonkoma area. So if you know Long island, if you go out the Long Island Expressway, it sort of stops, or at least then it stopped in Ronkonkoma. What had happened is that families closer in to the city, in Brooklyn and the Bronx, would pile in the car on Sundays and go there. They also thought, "We've got to get out of the city. We need a better place to raise our children," and they would end up moving out here to an area that had been a resort area in the '20s. It had a lot of, frankly, substandard housing for year-round housing, and it was a little seedy. But people would move out there with the idea that they were creating this better life for their family.

Then, all of a sudden the husband would decide that he couldn't handle these two-hour commutes each way. Stress built on the family. They got overextended financially. The next thing you knew, the husband would leave, the wife would be stranded out there with two little kids, and there was no mass transit and no jobs in this former resort area, and it was terrible. It was not the usual sort of caseload. It was mostly women with two kids who were stuck out there. They couldn't afford to move. They owed money for the chain-link fence, and they owed money on the freezer plan, and they were in debt and never going to leave, and he wasn't paying the child support because he couldn't, and it was just a sad story repeated over and over and over.

It reinforced my interest in women's well-being and how women's well-being connects to child health and child well-being. It was a great year, actually. I learned a lot, had some terrific experiences. I was green as grass. I had a wonderful supervisor in my social-work unit, so I actually did learn something about what I was doing. I didn't just process papers; I did everything. I mean, after that, the organization moved to a system in which some people did intake and some people did case management. We did it all. You went out, you started up cases and you managed them.

And you saw sad, sad situations. I went to a house one time to open an old-age assistance case in which the mother-in-law was living with a family, and it was a sad, sad story. She and the daughter-in-law couldn't come in for intake because they only had one pair of shoes between them. They couldn't both go out at the same time. They didn't know they could open a case with her still living in the family, so they had waited this long because they thought she'd have to move out before they could get assistance.

Harden: Tell me how you got from Long Island to Kentucky and made a decision to pursue advanced degrees.

Baldwin: I was getting a divorce. I had written to a colleague when I was an undergraduate, who is now at Kentucky, just to say the marriage didn't work out. I had a Mexican divorce. I came back that night from Mexico, and when I came into my apartment, the phone was ringing. It was this friend, who said, "I got your letter. You need to come to graduate school. That would be the best thing for you. I'd always thought you should go to graduate school." He'd been on the faculty with a master's degree at Stetson and now was getting his Ph.D. at Kentucky. "I always thought you should go to graduate school. I've had them hold an assistantship for you. I know you can do it. You ought to come. The papers are in the mail." And I thought, "Okay. Seems like a good idea. I need a change." I dictated my cases, sold my furniture, loaded two cats into a sports car, and headed off to Kentucky.

I went to the registrar, and the registrar said, "I'm sorry, you haven't been admitted to the university." And I said, "But here's my letter about this assistantship. That comes from the department." But the registrar insisted, "You have to be admitted to the university first, and you haven't been." It was so awful that I thought, "Well, I'm not going to think about that today. I'll come back tomorrow." It was five o'clock pm.

So I went in the next day and said, "It's possible that you misfiled those papers. Could you just look again because it's really important to me right now," and they did, and they found them. That was not an auspicious start to my career at Kentucky, but it picked up after that. This was good.

Kentucky had a thesis-bypass program, so if you came in with a bachelor's degree and you did as well as people who came in with a master's degree, they let you move right on to the Ph.D., and that's what I did.

Harden: Were there particular professors or particular courses that stand out in your memory?

Baldwin: Yes. I had a major professor who worked in fertility research who was just amazing. He was wonderful. He said one day, "There's this man out in western Kentucky who wants to support research projects. He wants to talk to us." And he said, "If we get this grant, then I want you to work on it, so I'm going out to talk with him about it. Do you want to come?" And there were two of us, actually, and we said, "Sure." So he said, "Okay, meet me at the airfield at the university at six a.m." We went out to the airfield and discovered that this professor was a pilot. He had a little four-seater plane, and because it was a cold time of year, they had to jump-start the plane. I was not used to private planes where you might have to jump-start the plane to get it going.

But he piled us in this plane, and we flew to western Kentucky. We met with this guy who wanted to do the study. And he finally said, "So, how much would this cost?" and my professor says, "Well, this is what it would cost us to train the interviewers and collect the data and analyze the data." He said, "That sounds reasonable." Wrote a check. And we said, "Thank you very much," and we got back in the airplane and flew back to Lexington. And I thought, "That was interesting!" Little did I know how unusual an experience that was. I didn't know.

I trained the interviewers, and we collected the data and analyzed it. It was a tremendous experience. I had a lot of fun. When I was at UK in the summers, I did a lot of interviewing in Appalachia, and it was wonderful. It's a different world. A marvelous experience.

Harden: You got your Ph.D. in 1973, and then you came straight here to the National Institute of Child Health and Human Development. Why here? Why did you choose to come here?

Baldwin: I have described my life as a paragon of non-planning. I mean, I'm a poster child for "don't plan your career."

I had been in Colombia working on my dissertation in Bogota, and my major professor got sent to Colombia just when I was going to do my dissertation. This was not a good thing, actually. He said he had a childhood friend who is a branch chief at NIH -- I'd never heard of NIH -- and that this guy was recruiting to fill a position, and I should go interview. That would be a good thing. "And say hello to Jerry while you're there." I said, "I don't want to do that." I was applying for other jobs because I wanted to do research in reproductive health.

And so then I got a letter that said, "Have you talked with Jerry? He's one of my oldest friends and you really ought to see him." I thought, "Well, why not? I don't want to be rude," even though my mental image of Washington had been fixed in the 1960s, with the riots.

So I came. I flew into National. He picked me up and drove me out to Bethesda. It was springtime. NIH was a campus. There were burbling brooks, there were flowering trees. I'm thought, "Wow, this is really incredible!" And then I started to learn about the job. I guarantee you that 99.9 percent of people in academia have no idea what you do as a research administrator, zero. So, of course, I didn't either. I listened to the job description and I said, "You know, I've been out of the country for a year, and this sounds really exciting. I think I could do this." And it was only a two-year contract, so I thought, you know, two years. That ought to be fun. My husband said, "You worked so hard for the Ph.D.–we'll go wherever you want to go." And so we came here on a two-year appointment.

Harden: And here you are still.

Baldwin: And here I am, 30 years later.

Harden: Would you describe the climate when you arrived to be a research administrator? This was a time, in 1973, when there was a lot going on. President Richard Nixon was trying to rein in the NIH, and Drs. Robert Marston and Robert Stone were in and out very quickly as NIH directors. What was your first impression of this situation?

Baldwin: I was very much occupied with work in my branch. I was oblivious to things that were happening, larger issues happening at the NIH. I was not oblivious to the fact that I came in not long before Watergate. I was amazed, and I actually learned a very important lesson then, which is that there can be a great deal of turbulence at high levels of government, and yet the basic work of NIH goes on. That is one of the tremendous strengths here: we have a mission, people know their jobs, people do their jobs, and there can be all kinds of turbulence going on around you, but you essentially say, "Yeah, yeah, yeah, but I've got a job to do," and you do your job. I think I learned more about what it means to be a Civil Servant because I came in at a very turbulent time than I might have arriving at some other time. I've had a job to do. My job was to lead this research piece, this little piece of the portfolio that I have, and that's what I focused on.

Harden: Tell me about that job. As you said, many people don't know what a health sciences administrator does.

Baldwin: The way I can explain it best is with the adolescent reproductive health activities. I can still remember the day that the deputy director of our center came down the hall and said, "Wendy, look. The latest fertility data are in. Aren't these interesting?" It was wonderful having other demographers to work with there.

We sat down and looked at the latest fertility stats where the fertility, the birth rate to adolescents was going down, but the numbers were going up pretty dramatically because of the aging of the baby boom. And we thought, "Hmm. I wonder -- that's going to have an impact on child health because we know things about adolescent moms," and we just started to put the pieces together in a very orderly way about what the issues might be. We would scour the data, we'd look to see what was known, we'd discover there were whole areas where not much seemed to be known. We started to bring in outside panels to help us sketch out what we knew about consequences. Why does the mother's age make a difference to the outcome of the baby? Why does having a baby at a young age make a difference for the mom? And we even worried about the fathers.

This was an era when adolescent reproduction was of huge political and public interest, so Congress got interested and had hearings, and the department developed an Office of Adolescent Pregnancy Programs, and the press, of course, always liked to write about this.

Harden: What years are we talking about now, roughly?

Baldwin: Middle 1970s. There was a tremendous amount happening. As health science administrators, we were saying, "Wait a minute. These issues have implications for society and policy and programs. Our job is the science. What does science tell us? And if it doesn't have the answers, what are we going to do to put the answers in place?

So I had the great good fortune to be able to basically build a whole program of research. We identified areas of need, we put out solicitations, we basically built the story piece by piece with the scientific community. I did a lot of writing.

I didn't do it -- you have to be very careful in these jobs not to be in competition with your grantees and contractors. That's quite risky, inappropriate, risky. And I don't think we ever did that. [Dr. Baldwin–please clarify: when you said, "I didn't do it," did you mean that you didn't do the scientific studies yourself or something else? I am unclear as to what you might do as an administrator that would put you in competition with your grantees and contractors.]

We stayed true to our course, which was to provide that overview and to be the "fact person." I can't tell you how many hearings I've participated in where I was invited as the "fact person." What do they tell the next panel? You're here as the "unfounded-opinion person"? I don't know. But I was always the "fact person." My job was to lay out what is known, what isn't known, what the effects are that need study.

As the studies were done, we learned you can take the investigations a step further. First you studied the obvious things: effect on the baby or the mom. Then you examined the next effect: effect on society, effect on families, tremendous effect on grandmothers of adolescent childbearing because, frankly, they're the ones raising the kids. And odd things you'd see in the day, that children born to very young moms did better than children born to slightly older moms. That doesn't make sense. Why would you do better if you're born to a 15-year-old than a 17-year-old? Well, because the child born to a 15-year-old, the family says, "Oh, my God, we have to all help take care of this baby and raise this baby." The 17-year-old, they're much more likely to say, "You made your bed. You have to lie in it and take care of that baby." And so the baby of the 15-year-old was actually being raised by a 35-year-old, and the baby of the 17-year-old was being raised by a 17-year-old. But things that are superficial in the data aren't always true. You have to sort it out a little.

Harden: When you became the branch chief in 1979, you worked to pull together into one research program the previously separated demographic community and the child development community with the U.S. Census Bureau in order to achieve the goal of developing survey instruments and collect national data. Can you tell me some more about this initiative?

Baldwin: Yes. Actually, this is an amazing era in that the Labor Department had a study called *National Survey of Youth Employment*, and their goal was to track a cohort of men and women between the ages of 14 and 21 and track them for, say, 10, 15 years as they entered the labor market. Their job was to watch them as they progressed through the labor market. And we know that how men and women are moving through the labor market influences fertility behavior, including behavior about willingness to get pregnant, what you do when you become pregnant, what the effects are on the children, do you have health insurance or you don't, can you care for the child or not. So we thought, it would be great if we could have fertility data collected along that.

The initial reaction from the Labor Department was, "Leave us alone, we have our study. Leave us alone." We worked on them for a while, and they finally said, "All right, we see your point. Maybe this is okay to do," and since we paid for it, we got wonderful data about childbearing patterns and reproductive health.

But all during this time, we saw that there were two communities. One was the demography community that was looking at broad processes, and they really did a fabulous job of understanding how you could be representative of the population so that you could have results that were robust and generalizable. But they had terrible measures of effects on the children. They had things like birth weight. That was their outcome measure. The child development community had wonderful measures of outcomes on children, behavioral assessments, developmental assessments, but they had terrible samples. They just had collections of kids.

And so we thought it would be wonderful to get those communities to work together. So here was a strategy. We'll put behavioral assessments of the children, of this cohort, in place. Then you'll have representative samples, big samples, like 12,000, and you will know about family and employment, and then you'll not just know they had kids or what the birth weight was, but you'll actually know what their development is. We'll go in and observe the babies of these people. They're all across the country. And the Labor Department said -- they'd come around on this one, because they'd discovered that adding our indicators made their studies more interesting, so they had very high retention rates. We had about 95 percent retention after five or six years of studying them.

So then we said, "We want to come and observe the children." We got the usual reply: "Oh, no, you can't do that," after which they eventually came around. We worked with a developmental psychologist to find which measures could be done in the home and were useful, and it basically changed the whole research landscape, because now the developmental psychologists and the demographers needed each other because now they had a wonderful tool to work with, but each one of them didn't understand the other's side of the effort well, and so we saw a tremendously effective team build up in the community. It taught me a lesson about interdisciplinary research, which is, you can't just talk about it and exhort people to do it. You have to put out tools and strategies that make people work with another constituency because they need an insight that the other group brings. Once we did that, it was tremendous for that field. It was a lot of fun.

Harden: During this time, though, from 1979 to 1991 -- this is the Reagan-Bush era in the White House, and the country was becoming much more conservative -- you were involved with the study on the causes and consequences of adolescent fertility behavior, which was proposed and funded and then rescinded. Would you tell me about this?

Baldwin: In the beginning of the AIDS epidemic, the Institute of Medicine issued a report about the need for a national agenda to understand this brand-new disease. No one understood it well, but we had figured out that it was sexually transmitted. [Dr. Baldwin: is the following sentence correct? It didn't transcribe clearly. Please fix if I got it wrong:] One of the study sections dealing with AIDS observed that we did not understand the demography of sexual behavior. Despite decades of work in fertility, fertility research at that time had basically nothing to do with sexual behavior. I know that sounds odd, but that was true. And so we looked at this, and it seemed obvious that AIDS was developing into a crisis. We realized that we had the scientific and intellectual tools to do research on sexual demography: the range of behaviors, the patterns of behaviors, how people accept and adopt them, etc. And so we set out to do that. And as you pointed out, this was a political era in which such a study was hugely controversial.

We started with adults, and we were criticized by people who made the argument that by studying sexual behavior in light of AIDS, where we had to ask about sexual practices, we would encourage those practices, specifically homosexuality. Well, there was nothing that could be further from the truth, but that was a very difficult time. We basically couldn't do the adult study. We did a pretest for it, and some foundation money finally funded a much smaller sample than we would have done. It was heartbreaking because it was a time when the scientific community, broadly construed, needed such basic information, and I think the problem came from a fundamental misunderstanding as to what causes behaviors to develop, to be sustained, or to be changed. And I'd like to say that the world's a different place now, but I don't think it is. I think we still greatly lack scientific insights as to just how people adopt behaviors, sustain behaviors, change behaviors at the most general basic level.

Harden: I'm interested to hear how you, as a trained scientist, think about this, because science only exists within the social context, and, in the case of government-funded science, it is subject to political pressures.

Baldwin: Always, and it always will be. This is why certain areas of research have a much more difficult time, because I don't think anyone believes that a higher being has an opinion about blood pressure, but many people feel that a higher being has an opinion about sexual behavior. So it's not the same. You can't study it the same way, you can't treat it the same way.

The problem is, if you don't invest in an understanding of basic behavior, of what causes behaviors to be adopted, sustained, changed, you fall into two traps. One is, if I ask you about a deviant behavior, it might cause you to do it. The flip side of that is, if I don't want you to do something, if I put a poster up that says "Don't Do It," that's a behavioral intervention. If that's not a behavioral intervention, and if I ask you about a deviant behavior, that would not be what provoked you to do it. But it's a superficial understanding of behavior that leads us to weak interventions and it stops us from doing research because of this unfounded fear that you will then cause the behavior that you're trying to study.

Harden: Is the best course for this kind of science to continue to fight the battles with federal money, or would it be better to try to find a private patron who can write a check to fund it with no government oversight?

Baldwin: You can certainly find a private patron for a project. But this is a fundamental piece of research, that is essential for everything else that we do, and to cut it off from federal funding would be highly inappropriate. You have to just tough it out, fight the battles, try to explain it again and again.

We know there are behavioral components to many, many other diseases that also have biological components, and so we have to study them together. And if the NIH were ever to divorce the behavioral out of the biological, that would be a true tragedy. They could do more, but you can't divorce it out, separate it from the other factors. We don't do enough, I don't think.

Harden: Well, that, of course, has been another argument off and on about behavioral sciences and laboratory sciences and what the focus of NIH research should be. I think there's no way to escape the philosophical questions when you're dealing with things like this.

Baldwin: Absolutely. You can't escape them. Science has been filled with philosophical questions like that forever. It's just that once we agree on one of them, we tend to forget how difficult the struggle was to come to agreement. We've got to remember that there was a time where it was considered inappropriate to do an autopsy. Well, we've gotten over that one. Transfusions were also considered inappropriate. Transplants. Our conception of what is acceptable and appropriate for science is not fixed; it changes.

Harden: Certainly.

Baldwin: And it's changing even now.

Harden: And there are still groups, of course, who object to transfusion and transplantation, so even those medical actions are not something that is supported universally.

Baldwin: You can't wait for no one to object to what you do. There has to be a more thoughtful approach.

Harden: In 1993, in June, you were named Acting Deputy Director for Extramural Research, I presume by Dr. Bernadine Healy just before she left. And then after a year, when Dr. Harold Varmus arrived, he appointed you as permanent Deputy Director, so you were moving from an institute here to Building 1 and looking at the NIH grants program from a broader perspective. Would you describe your main responsibilities that first year and what your goals were? What did you find and where did you want to go at the very beginning?

Baldwin: When I came at the very beginning, I came on a six-month detail because I had a perfectly good job that I liked. I had no desire to make a change, wouldn't apply for it. But when Dr. Healy asked me to do it on a detail, I felt, "Well, how can I say no? I'm sure I will learn. I've always learned something from any kind of new opportunity like that," and it was only for six months, so how bad could it be?

When I came over, there was no transition. John Davis left on a Friday and I came on Monday. That was it. And it was then after Harold Varmus came that I really started to get into the rhythm of this job, and then when he asked me to do it permanently, I agreed, because then I could see what the job was. I didn't really know what the job was. I didn't really know what the job was when I agreed to do this. All I knew was that John Davis never seemed to have any time and seemed to work long hours, and then I understood why.

It's a totally different experience being in the OD [Office of the Director] than it is being in an Institute. I had tried to have opportunities for people to do rotations or do details over here, because if you only live your life in an institute, you have missed out on a lot of what the NIH does. People don't always like it when the OD does something because that frequently means we reach back into the institute and tell them something they have to do or something they have to pay for. On the other hand, the OD is a buffer. It's a point of contact, it's a buffer for the institute, it's the glue that kind of holds the whole of the NIH together, because the institutes are terrific. They develop their programs, their initiatives, as they should. But that doesn't create a coherent *the NIH*, and somebody has to do that, and that falls to the OD. It's really fun because you get to work on cross-cutting issues. It broadened me tremendously because I said, okay, it's time to step away from my longtime commitment to issues of child health and women and reproduction and take on a broader array of issues. That was fun. I guess I'd done the other long enough that I was able to see that as an opportunity and not that I was giving up things I loved. I was taking on new things.

Also, you get to deal with the problems that can't get solved in the institutes, and since the institutes are filled with a lot of smart people, only compelling problems end up here, and that's fun. The excitement of science is solving problems, and the nature of these jobs is solving problems. It's a different level of understanding. Frankly, sociology and demography are great training grounds for this because it gives you a background in understanding group behavior-- incentives and motivations for groups, not individuals. It's not individually oriented. And then demography gives you quantitative skills, which are absolutely essential.

Harden: Would you describe the differences between what the Office of Extramural Research does and what the Center for Scientific Review does and how they relate?

Baldwin: Let's roll the tape back a little bit here to say the time of the Cassman committee -- [Dr. Martin] Marty Cassman chaired a committee when [Dr. Gerald] Jerry Green retired from DRG [Division of Research Grants; now the Center for Scientific Review, or CSR]-- to look at DRG, and DRG did two things at that time. It did scientific review and the things that go with that, and it also did the data system IMPAC, which tracked extramural grants. The recommendation from that committee was IMPAC should move into the Office of Extramural Research because it's a data system to support extramural research, not to support review. Also it was in grave need of refurbishing because it was a very old, flat mainframe database and it needed to be modernized. So IMPAC moved over here, and that left CSR able to focus on its true mission, which is scientific review.

Every grant application at intake comes in through CSR. It gets assigned to a review group, assigned to an institutes, and CSR manages the scientific review for about 70 percent of those applications, regardless of where they're assigned afterwards, and 30 percent of the review _____ institutes [Dr. Baldwin: the transcription for the previous sentence was unclear. Please correct as needed.] Once the review is done and the summary statement written, that closes the books for CSR. The grant moves on to become the responsibility of an institute which makes a funding decision about the grant, and then, if awarded, to monitor it and shepherd it through its course.

The Office of Extramural Research [OER], on the other hand, is much more responsible for the policy and procedure envelope within which extramural activities get done. So in terms of the grants policy statement -- that's the legal framework within which we make our awards -- and our articulation of the OMB [Office of Management and Budget] circulars that detail the financial relationship between the federal government and universities that is held within the OER, that applies all across the board. The *NIH Guide*, is *the* tool -- we have a special exception so that we can use the *NIH Guide* to communicate research opportunities to the external community, not the *Federal Register.* This is wonderful because the *NIH Guide* is a document that is specifically focused on our community. When I came here, we sent out 14,000 of these a week. Now it's all done electronically.

So OER has a policy responsibility. The SBIR [Small Business Innovation Research] program is an example because we have an office, basically one person, who is responsible for the solicitation, for dealing with the Small Business Administration, for outreach. When you do outreach, you can't do it targeting people interested in small business initiatives to help kidney disease. You must focus in general on how small businesses deal with the NIH. All of the institutes, on the other hand, fund small business grants by figuring out what their topical areas are. They're the implementing arm. We're sort of like the glue arm here.

And then we have what I call the SWAT team in my office, where we deal with big issues that come along that are NIH issues. They don't live in one institute. They have to have high-level attention. Last year I did stem-cell implementation. In the past, I did the Tuskegee apology. D.A. Henderson and I led the review of human radiation experiments for the department [Department of Health and Human Services, DHHS]. All of these are issues that may reach into individual institutes but need a trans-NIH location for their resolution, and that's typically been here.

Harden: I want to talk further about some of these specific things. Let's go to one of them, the human radiation experiments, the NIH response to the presidential-level committee that was looking into this subject. Would you elaborate on the challenge of producing these records and comment on the impact the effort made on NIH?

Baldwin: Yes. Sometimes when problems come to us, they take a week. We may drop everything and work on them for a week. This one we worked on for almost two years, and even hired staff to work on it. The presidential commission really was looking back at what had been done in the federal government on experimenting with people using ionizing radiation. I may have a somewhat jaundiced view of this, but I will say that, by and large, what we learned was, yes, there were some egregious cases and there were some cases that were not egregious. They were all known, they'd all been documented, they were out in the literature. I would be hard pressed to say that we learned anything new about research experiments done during the preceding 40 to 50 years.

Harden: Are you talking just about NIH research or about all research in the United States?

Baldwin: In the United States. Much attention had already been given to these studies and to these problems. In my view, the more egregious cases were occupational cases, not research cases.

We had some funny moments during this project. In one case people were horrified to discover the study had no informed consent, and it consisted of a sample size of one. The principal investigator was the research subject. So you look at that and you think, "Yes, you're right. There was no informed-consent document. But I think I understand why."

We learned a lot about going back and looking at historical records. Can you find the IRB [Institutional Review Board] minutes from 30 years ago? Can you find out what's in our research records from 40 years ago? I would encourage everyone to follow the Records Retention Act. If you don't follow the Records Retention Act, let me tell you what happens. You take a document that is a draft where you scribbled in the margin, "Better talk to John about that." Okay? Three drafts later, you get to the final MOU [Memorandum of Understanding], which is signed by both parties. Now, because you don't follow the Records Retention Act, you retain that earlier draft with "Better talk with John about that" in the margin. Forty years later, somebody comes along, has to review these records, and is trying to puzzle through what you meant. Now, in fact, it may mean that during the discussion of this MOU, somebody said they were going to play golf this weekend, and you said to yourself, "I'd better talk to John about that," and you scribbled it in the margin. Maybe it means this clause is so damaging to science and research that you'd better talk to John about that. But no one will ever know. But someone will have to puzzle through it. So please follow the Records Retention Act.

Harden: I look at it from a different point of view. As a historian, I want to read all those marginal notes!

Baldwin: We worked for two years on this. We had field hearings. I think the estimate was that overall-- and most were done by the Department of Energy -- we spent $30 million on those. We were prepared with the five-volume report, and we set a press conference for, let's say, a Thursday at two o'clock. Wednesday, we were all sitting around the office, and someone had a radio on and they said, "Don't you have a press conference scheduled tomorrow?" and I said, "Yes." They said, "Well, you've got competition." I said, "What do you mean?" They said, "The O.J. Simpson jury is coming back tomorrow at two o'clock." I called the guys at Energy and said, "You know, do you think anybody is going to come to our press conference?" They thought I was making it up. They said, "This can't be." I said, "Well, it is." So we pushed our press conference forward to noon. We had it. Only about four people came. No one paid any attention to it. There's a lesson there.

Harden: You also addressed the problems of management deficiencies in several institutes, specifically with the problem of payback of loans by trainees. Would you talk about this kind of problem and how you addressed it?

Baldwin: This is an interesting case because the National Research Service Act has gone through different eras where there were different payback requirements when we paid to help support people's training. And what we have found is that -- actually the GAO [General Accounting Office] helped us fund a study of this -- not all the institutes were paying quite enough attention to this. When they had someone tracking down required payback, the job frequently devolved to a collateral duty or a low GS level and it really did not get much attention, so we really had a huge backlog. It was quite uneven across the institutes, and the situation constituted a material deficiency.

I also learned you can get exempted from payback, and those cases in which there was a request for exemption came to me. That was often a really a sad situation because here would be a young adult who had been trained in biomedicine yet could not get a job that would qualify to pay back the investment through service. Picture this. This person has been through years and years and years of training. He or she can pay the cost of the training back by working in the profession, and for some reason they can't do it. Then you have to pay back in cash or you have to get exempted. What sad, sad situations they were, because basically when young adults cannot be employed in their professions it's because they've been in some horrible accident and are disabled or because of mental illness. It's everything we would know from looking at the morbidity statistics. But when you see the cases and the doctors' certificates as to how disabled this person is, this is very sad. Someone has invested a decade or more of their life training in a field that they care about, in a field that needs people, and yet they can't work.

Then there's the bureaucratic side of this, in which you have to track this information down. You have to find out why those people aren't paying back. So, in fact, NIGMS [National Institute of General Medical Sciences] already had a partial payment center, and OER took on as a service basically to the NIH to clear up the backlog and then our effort will go out of existence. Many things OER takes on are with the idea that we'll do them for a period of time, after which they will end. A project either matures and goes on to live someplace else, or it ends because we've solved it. In the case of the training payback issue, over time we'll clear the backlog. The institutes are helping us support this financially.

Harden: It was during your tenure as Deputy Director here, if I'm correct, that the Grants Application Project moved from a paper-based to a digital- based process.

Baldwin: You've got it.

Harden: You and your staff both won several awards for your efforts in doing this, and I'd like you to tell me about it.

Baldwin: It's been a lot of fun, frustrating and fun. The last few years, say five, have really been an era of that transition. We took the huge paper process of [Dr. Baldwin–I turned the tape over here and lost some words. Can you identify the first effort you made in converting from a paper to electronic process?] _____ and said, "How are we going to do this better and do it electronically?" We started by acknowledging that our underlying process was archaic, developed with old technology, and it had little ornaments hung on it from year to year to year, but it needed to move into the contemporary realm. That was my first effort in transitioning to electronic formats.

The other piece of this was involved with invention reporting. We had a horrible paper-based system, a little office, stacks of paper, and we developed Edison, is the interactive system to do invention reporting -- Edison--invention, get it? A little joke there. And it has now become the government standard. There are some 16 other federal agencies that use our system, and we are now getting requests from states who want to adopt it.

We got our toes wet in this. I started with a fundamental principle, which was, we had to get our house in order and handle information electronically to do business within the NIH before we could annoy institutions and ask them to send grant applications to us electronically, because we make awards to institutions. We knew that institutions would have to change their behavior in order to deal with us electronically. This became a little issue out there because some agencies, and certainly foundations that deal with individuals, would just say, "E-mail it to us" or "Send it on the web," which is really simple if you're getting an application from an individual. It is not so simple when you're asking an institution to alter their whole system. So our system has been slower to roll out than some others have, but we've built our back end so that we're dealing with all of these things electronically now behind the scenes.

As a historian, you'll appreciate how the Electronic Council Book developed. When I first came to the NIH, we sent paper summary statements of every project to every Advisory Council member. By the end of the second day of Council, you literally could not see across the Council book table because it was heaped with pink sheets. Now a Council member gets access to an electronic Web site. We activate it when the material is available, or they can get it on CD. They get to scan things. They get summaries. They can say, "I want to see everything with a human-subjects flag." Those would pop up. They can always get the complete information down to the application if they want it.

We've given them a vast amount of information electronically and organized in a way that they can use it so they can actually find issues they might want to pursue. My theory is, if I have one piece of paper that you might be troubled by, the best way to make sure you don't find that is to give you 5,000 pieces of paper. What are the odds of your finding it? If I give it to you in electronic, searchable form and you know there's something you're concerned about, your chances of finding that are just about 100 percent. So we've taken the process from being paper-intensive, burdensome, mailing paper out, receive return paper, etc., and we've turned it into a system that gives people easy access to better information. It's also cheaper, and that's the hallmark of what we're trying to do.

The actual grant application is the last piece. I said from the day we started this, "The last piece of this puzzle that will fall in place is receiving the grant application electronically," and that's was true.

First of all, you need to do business with the people you're already funding before you worry about getting the stuff in from people who apply. This is a long, long, long story. But it's been an amazing transformation.

I will bet you there are a lot of people on the campus who don't even remember what life was like 10 years ago when you could only see within your institute and you got IMPAC format on your screen that was uninterpretable. Now I can sit at my machine and pull up summary statements, I can pull up notices of grant awards, I can look at a grant funding history for any investigator, regardless of which institute funds it.

Harden: We need to go one more step here. What's happening to archive that electronic information? The reason I ask is that when people want to access grants from CRISP, they do not get the award page, they do not get the summary statement.

Baldwin: CRISP is the public face of this information.

Harden: Yes. I'm well aware.

Baldwin: What I'm talking about is the internal face.

Harden: Precisely. And so my questions are whether you are archiving that internal information and whether it will eventually be made public. For example, the NIH Freedom of Information Officer would like CRISP to include the award amount because at present, people must submit a FOIA inquiry to get a statement of the award amounts and this must be mailed out on paper. Similarly, scholars want access to the pink sheets to learn how the peers of the applicants assessed the proposals.

Baldwin: Yes, the information is archived. We took the dollar amounts off the CRISP database, oh, six years ago, maybe, because of the "mischief factor." If you go to the budget page and you say, "I'm interested in what we're spending on lupus," and you look down the table and you see lupus and you see a dollar figure, that dollar figure has been vetted by the institute as the dollars actually associated with lupus. CRISP, on the other hand, is designed to tell you substantively about the work we're funding. It helps people find potential collaborators, see what areas are hot. It has a lot of uses. If you went to CRISP and typed in lupus, it would pull up every abstract that either had lupus in it or was coded for it. But that would not necessarily tell you about our portfolio of research relevant to lupus because there might be other work that is looking at a certain receptor, which in fact we all think is going to be key to understanding lupus. So the institute says that's lupus, but CRISP would not. Or it could be a project that's working on lupus and four other things, so people may conclude that lupus represents only 20 percent of that project. When you want accurate dollar amounts spent on particular diseases, you want figures reported by the budget office. They are institute-vetted numbers of dollars associated with diseases. You should not be using CRISP to get that figure.

You should use CRISP to learn about the substance of the individual projects. Say you are interested in whether a grant is a big project or a small project. Is it an RO3? It's a small project. Is it a PL1? It's a big project." There are other ways to get to the dollars. But to link dollars with CRISP abstracts was leading people to erroneous conclusions about what we were doing. In a way, that was never the purpose of CRISP. So we said, "Since that wasn't the purpose and it's creating confusion, we'll take it off. Not a problem."

Harden: But, on the other hand, one would like to see an archive of individual grants so that one can follow individual investigators and their work over time.

Baldwin: You can't follow the dollar amounts. But, again, you would only follow the dollar amounts if Dr. X was the principal investigator.

Harden: That's right.

Baldwin: So if I'm the principal investigator on one study for $100,000 and I'm sub-project director on a PL1, you don't know that.

Harden: Well, I understand. But I'm thinking of a different way of looking at things.

Baldwin: I know, I understand. But you are asking a different question than the data systems were ever structured to answer. Internally, we can probably beat that out of the system. We don't publish information electronically that would permit you to track an individual's funding over time. And even with what we do track, it would be very hard to identify those dollars that are associated with a person who is on a sub-project or a subcontract, so you would only get a partial picture. But you can certainly track their history as a principal investigator if you wish.

Harden: Tell me about the trans-institute Bioengineering Consortium.

Baldwin: One of my favorite activities. I hadn't been in this job very long when Bob Nerem came to visit me as a representative of the bioengineering community, and he said, "Our community has been looking at our interactions with the NIH, and we think bioengineering has a lot to offer to the NIH, and we're not happy." And I said, "So tell me why you're not happy." And he said, "I just happen to have a report here, and a bill of particulars." Whoa. Usually people just come in and complain. He came in with this analysis, and here were the problems: We don't know what the vision is for bioengineering at the NIH. We don't know what your goals are. We have no idea where you want to see this go as a field. It's scattered. We're appreciative of the fact that all the institutes fund some bioengineering, but it can mean you have to go 20 different places to figure out who wants to fund it or what's funded. There aren't appropriate bioengineers in the study sections. There aren't mechanisms that are appropriate for the kind of work that bioengineers need to do. And I thought, "Oh, my goodness. It looks like someone has actually analyzed the problem and identified real issues."

So I first went asked the institutes if they wanted to be a home for bioengineering activities and take on a leadership role. Several stepped forward. But I also said, "How would you handle this if you did it?" And each one of them planned to handle it the way they already handled bioengineering in their institute. They did not address how they would do this for the whole NIH. Their answers were good, but they weren't great.

I went to Harold Varmus and I suggested that I put together a consortium. All the institutes would come to the table, and we would address the issues the bioengineering community has brought up. We would not tinker around with things institutes are already doing, but we would try to address cross-cutting issues. I thought we could try this for two years. By then we could see whether bioengineering should go to one institute, should become something else, should be disbanded, whatever. He agreed, so BCON was invented, the Bioengineering Consortium.

This has been one of the best things I have been associated with over here as deputy director. The institutes each sent a fabulous person. They each had someone who was responsible for their little portfolio or big portfolio, as the case may have been. All of a sudden they weren't just representing one little piece of the entire institute portfolio. They had been given a chance to think about bioengineering in a way that galvanized them and made them want to come to work in the morning. It was a way to think about bioengineering for the whole of the NIH.

The first thing we did was to put on a symposium, which served as our "vision" meeting. The idea was to identify are the areas of bioengineering most valuable to the NIH. We had fabulous speakers. And I will never forget going to the IC [Institutes and Centers] meeting, maybe two weeks before the symposium, and saying, "You know, we are not reserving a bloc of seats for all directors. We'd like to have institute directors come, but you're going to have to tell me by the end of the day because we have all of the Natcher Building auditorium, but we are oversubscribed. I can't hold seats for you unless I know you actually want to come." I had never before gone and said to the directors, "If you don't tell me by the end of the day, you can't have a seat because we have so many people coming." We had a sellout crowd. We had one every year we did this.

This first meeting set an agenda for NIH in bioengineering research. The community first said, "We want centers." They were so thoughtful in their discussions. You could read the work group, the breakout-group reports and understand why they wanted the centers. The compelling issues in bioengineering were not ones that a single person at the bench was going to solve. They were ones that you and I and somebody from a private company and somebody from a university a thousand miles away had to work on in order to advance, and the NIH was not usually receptive to that kind of a project. They were bigger, they were more expensive, and they didn't look like R01's [investigator-initiated grants]. So we invented a new mechanism: the bioengineering research partnership. To win one, you couldn't propose a project that could be done by one person at the bench. You had to pose a question that was bigger. You had to be posing one of these large questions and putting a team together.

Then I went back to the institutes and asked, "Who's going to put money in it?" In the end we had commitments of $20 million. When the applications came in, they were so good, the institutes funded $40 million worth of them, and it's grown every year, because it fit a need, and it wasn't heavy-handed. People said, "What's a partnership?" and I said, "I don't know. I know what it isn't. It's your job to tell me what it is. You said you needed this thing that isn't an RO1. Now, you tell me what you have to glue together, in fact, to do these projects."

It was really fun, and the bioengineering community at the NIH, by which I mean the whole community in all the institutes, is a wonderful community to work with. They're really dedicated. They'll take on hard tasks, they really work hard, and they have a huge amount to show for it, just a tremendous amount to show for it. And so it was a very positive experience.

The acid test -- BCON meets once a month, two hours, three to five. I never missed a meeting, I don't think, and I always came out of those meetings energized because we were tackling problems. We always had problems. But it was a very constructive, creative group setting about to tackle problems and to come up with something new that would deal with them. I went to a BCON meeting this week just to say goodbye to the group.

Harden: In June 1999, you testified before Congress about the Small Business Innovation Research (SBIR) program. You were requesting a doubling of the phase one funding amount from $100,000 to $200,000. Tell me a little about the SBIR program and the issues surrounding its funding here.

Baldwin: Boy, that's an interesting one. The federally mandated SBIR program is a set-aside of funds, on which we have to spend now 2 ½ percent of our research budget. In addition, there are certain requirements that qualifies applicant to be a small business, and there are guidelines about the size of the awards.

When I first came on board, our success rates were low and people were grumbling about why money had to go into this program. I spent a lot of time looking at the quality of the program and the stringency of the review, and I came away feeling that, in fact, it was a very robust program. If you think about a time continuum, we invest in basic science, and some of that -- not all -- some projects actually lead to inventions or products. A lot doesn't. Much of our investment goes to create basic knowledge that takes you one step closer to intervening in disease. But some projects actually take you to that step where there's going to be an intervention. And the small business program is a way to help that happen. It's a way to help small businesses be a part of this whole enterprise. And I would argue that taking an idea and actually turning it into something is an activity much better suited to the small business community than it is to either government or universities. So it's a great partnership. It really is a partnership. But it will only work in the context of the NIH if the small business community is held to the same standards–of rigorous peer review--as everyone else is. And I believed that was not always the case. There was also a problem with some of the guidelines, which drove us toward small projects when in fact much of the science was arguing for larger projects.

I went back to the Small Business Administration and said, "We want to mainstream the SBIR program at the NIH. I want it to walk and talk and look like everything else we do. I want the rigor in the peer review, I want the accountability. I'm going to treat it like every other project." And said that this was what they wanted, too. I also said, "I want the authority to let the funding be appropriate for the science. We fund everything else with funding appropriate for the work to be done. This is the only project, practically, where we artificially cap the funding, and it's driving us away from some areas in genomics, nanotechnology, some important clinical areas where the small businesses could play a real role. We're being driven away because we're not allowed to mainstream these programs like everything else." I got an agreement that we could treat those guidelines as not capped, but as guidelines. If we had a reason for it, we could fund at whatever the appropriate level was. I view this one as one of the most significant changes we've been able to effect. Most projects stay within the guidelines. But some of the ones we're able to fund are in important areas that you can't do within those guidelines, and I think it just goes to strengthen the program even more.

Harden: Is there any other major initiative that we haven't talked about that you would like to get on the record?

Baldwin: Let me go back to the human radiation experiments activity. We struggled through two years of rummaging around in records only to find that they didn't include some dramatic expose, they included dental x-rays from 30 years ago. I felt like we had to have something positive come out of this.

One of the lessons we learned is that what goes on in obtaining informed consent is not always totally informed, and it's not clear that it's true consent. That was the message that I took out of the work we did on the radiation experiments. I started to puzzle out why that is, because we have rules about it. But informed consent is a behavioral interaction. It is subject to scientific knowledge just as other behavioral interactions are. We apply science if it's an interaction to understand why people do or don't take their blood-pressure medicine. Why aren't we applying science to understand how the behavioral interaction of informed consent happens so that we can offer our scientists not just rules and exhortations but actual tools to do it better, to understand what happens? Why is it that some people don't hear what you say? Why is it people think they weren't told about the risks? How do you communicate risks in a way that people actually understand them? So we started a research program. And that really launched my personal interest in what the NIH role should take relative to some of the human-subjects issues. I'm not talking about the regulatory role, but the scientific role. We have now strengthened some requirements, and I think the work we did will improve the chances that this will all be done correctly.

The most significant thing is our Human Subjects Research Enhancement Program. We have a situation now where research is growing in volume, growing in complexity. More research is taking on more difficult topics, and yet most of our institutions are jammed up by a cap on administrative costs. It' s very hard for them to improve some of the systems in place even when they would like to. This program, which the institutes all came together to fund, is actually providing very modest awards, $100,000 to $250,000, to institutions specifically to support some direct-cost issues--data systems and computer networks, educational programs and training activities relative to human subjects. The research community in general, I think, has felt that there's been a great deal of criticism for how they're handling these issues, but nobody's actually stepped up to the plate to say, " I'd like to help you do it better." I think this is one of NIH's shining moments, when we said, "It is a partnership. We do want you to do it better, and we're actually going to be a material help in that."

Now, what are we getting back for this? We'll bring all those grantees together. The material they develop will be available to all. It's going to improve our protections of human subjects in a material way. And it's a first. I love firsts.

Harden: Is the University of Kentucky prepared for you? I say that only in part jest. Having listened to your account, it's hard to believe that anything after NIH would be as high pressure and as focused as what you have described. But why don't you tell me about what your goals are for the new challenge that you're moving into.

Baldwin: Well, I didn't go looking for them. The University of Kentucky came looking for me. Last spring, they came tap-tap-tapping, saying, "You know, we want a new vice president for research. We have a new president. The new president has a lot of ideas about how Kentucky is going to grow, strengthen. He's not naive about the problems we face, but he thinks we can do more and do better, and research is one of those areas. And it's going to be a new day." I'd already been using Kentucky as a model for how a state responded to the idea that it should do more.

The legislature had to put money up in a matching fund for endowed chairs and professorships. It's referred to as the "bucks-for-brains" initiative. They said, "We want to see our research universities strengthened. How should we do this? Maybe we ought to challenge them and help them put money out there to attract researchers." Clever reasoning, I'd say; not what all states do. I had held Kentucky out as a model for a state that had a genuinely constructive plan for how to start research. So when they came and they said, "Would you look at this?" I thought, "Yes, maybe I ought to."

You've noticed my life has not had the highest degree of focused planning on my part? Okay. So they came and I thought, " It's worth a look." I went to visit and was intrigued. They laid out what their vision was for UK. And you know, I need a new challenge. It's just time to do something new. My husband retired last year, my kids are out of the house, and I thought, "Maybe it's the right time to consider a challenge." And so I let myself start to think about the offer.

Now, in the midst of this, Dr. Elias Zerhouni arrived at NIH, and I believed that a lot of change would probably be coming, and the hook from Kentucky had already been sunk. I knew a number of the people that I'd be working with at UK, and they're terrific.

When you interview for a job like this, you basically do 48 hours of interviewing and you meet with everyone. You meet with the people under you, you meet with those who are lateral to you, you meet with the people above you, you meet with the faculty, you meet with the students. You meet with everybody. During my interview, I told them that I was going to be very frank about my views, and I asked the same of them. We needed to find out if we could work together during the short time I was there. Some people asked, for example, if indirect costs from UK research grants could be sent back to the dean's office, and I responded, "I don't plan to do that. First you'd have to understand what you were going to give up by having money come directly to you. Second, you'd have to tell me what you were going to do with the money. And, third, there'd have to be some accountability. But I'd be happy to sit down at the table and talk with you about that. If we can get over these three things, we could do this." I decided that if I couldn't be straightforward with them about how I'd view this job, I'd be of no use to them. I'd be a disappointment to them, and it would be a disappointment to me. But they said, "That's exactly what we want here," and the new president, Lee Todd, is really ready to make some changes and ready to see UK grow, and the faculty were too. When you're a change agent, you'd better hope other people are viewing you as a change agent, and preferably they are looking for a change agent. Will it work on the ground? Ask me in a year. Right now I'm getting an enthusiastic welcome, and I feel like it's a new lease on life.

I've had the most wonderful career at NIH. I've had a chance to do things you couldn't do anyplace else in the world. I've been allowed to continue my WHO [World Health Organization] work when I came over here. If institute directors can have a lab, I ought to be able to continue my WHO work, and Harold [Varmus] agreed. I have had the most rewarding experience. I've worked with some of the most wonderful people.

I worked with Phil Corfin [sp.] when he was deputy director. He was director of the Center for Population Research when I was there. The climate that I spent many years in can best be expressed by the fact that he won a *Ms.* magazine award for one of the 100 men who's done the most for women. He created a climate that was so supportive. I frequently went to activities where I was the youngest and I was the only woman. The mantra in NICHD was: if you can do the work, you've got the job. Nothing else mattered. It was wonderful. I've looked back on that. I have had a chance to be a part of some things that actually say made a difference for health science research. I've had so much fun, and I've had a wonderful staff. And for as much energy and excitement as I've had, I'm ready for change.

Harden: I would like very much to talk with you in a year or two and hear how things are going.

Baldwin: That would be great.

Harden: Thank you very much for talking with me, Dr. Baldwin.

END OF INTERVIEW